## Transcript for FDA Media Briefing Salmonella Outbreak Involving Certain Type of Tomatoes June 18, 2008

Coordinator:

Good afternoon and thank you for standing by at this time all participants are in a listen only mode after the presentation we will conduct a question and answer session. To ask a question at that time please press a star, then 1.

Today's conference is being recorded if you have any objections you may wish to disconnect at this time. Now I will turn the meeting over to Miss. Stephanie Kwisnek. Miss. - Ma'am you may begin.

Stephanie Kwisnek: Thank you very much. Ladies and gentlemen welcome I am Stephanie Kwisnek from the FDA's Office of Public Affairs. Thank you for joining us today and welcome to this briefing on the salmonella outbreak involving tomatoes.

Our two main speakers this after are Dr. David Acheson, FDA's Associate Commissioner for Foods and Dr. Robert Tauxe, Deputy Director of the Division of Foodborne Bacterial, Mycotic Diseases at the CDC. Our technical experts include from the FDA, Faye Feldstein acting Director, Office of Food Defense, Communication and Emergency Response, Center for Food Safety and Applied Nutrition and Mathew Eckle, Director of Office of the Americas, Office of International Programs. From the CDC, epidemiologist Dr. Casey Behrayesh.

We will have a brief question and answer segment after open-air remarks. At this time I'd like to turn it over to Dr. Acheson.

Dr. David Acheson: Thank you Stephanie this is David Acheson, Associate Commissioner for Foods at the FDA. I'd like to add my welcome to everybody. I know we're a

little later today than normal for which we apologize but we thought it important because we didn't have a call yesterday to update you with what we have.

The usual format, I will ask Dr. Tauxe to give you the CDC update and then he'll come back to me and I'll give you a brief update on what we have been doing with regards to tracing this problem back and then we can take some questions. So Rob I'll hand it over to you.

Dr. Robert Tauxe: Very good, thank you David. I want to start -- this is Dr. Robert Tauxe at the CDC. I want to start by recognizing the hard work of many in the states, the Indian Health Service, at FDA, and here at the CDC who have been working on this outbreak. CDC is continuing to receive reports of ill people in the outbreak of salmonella St. Paul infections. The most recent case that's been reported to us had the beginning of their illness on June 5th. We do not think the outbreak is over.

The first cluster of cases was reported to us from New Mexico in the week of May 22nd and thanks to the investigation by epidemiologists there the outbreak was linked to eating raw tomatoes within approximately one week. We will be updating the number of cases in just a moment. The number of cases has increased since the update on Monday and this rather - this increase in the number of ill persons reported is really not because there's been a large number of new infections reported it is mainly because some states have improved their surveillance for salmonella in response to this outbreak and because laboratory tests on many previously submitted strains have been completed now. Now I am going to turn the phone to Dr. Barton Behravesh for the actual numbers.

Dr. Casey Barton Behravesh: Hi this is Casey Barton Behravesh and so since April, 383 persons infected with the salmonella St. Paul having the exact same genetic or DNA fingerprint have been identified from a total of 30 states and the District of Columbia.

These case patients were identified because clinical laboratories in all states sent their salmonella strains from ill persons into the state public health laboratories for further characterization.

It's important to mention that the marked increase in the reported ill persons is not primarily due to a large number of new infections the number of reported ill persons has increased markedly mainly because some states improve surveillance for salmonella in response to this outbreak and because the laboratory identification of many of their previously submitted strains has now been completed.

So we have information on 243 persons and we have illnesses reported beginning on April 10th with the recent onset being June 5th. Our patients are ranging in age to less than one year up to 88 years and 47% of females. And we now have reports of at least 48 persons being hospitalized due to this illness. You can track our latest count and the counts by state on our Web site at www.CDC.gov.

Dr. Robert Tauxe: Thank you very much Dr. Barton Behravesh. And that's the update for the numbers that we have now. I should say that this number - these numbers, including the numbers by state are on the CDC Web site now live. Thanks very much.

Dr. David Acheson: Okay, thanks CDC for that update. This is David Acheson again from the FDA. The information from the FDA is that the trace back continues. We

have yet to make a definitive determination as to where these contaminated tomatoes have come from. As we've said on previous calls there is certainly a high likelihood that they came from Mexico or Florida and we have no information at this point to suggest that that assumption is incorrect.

As you know there are many places that have subsequently started harvesting tomatoes that are on our exclusion list, which is still posted on our Web, and being regularly update on FDA.gov. So I'm not able to tell you definitively yet where we - where the contaminated tomatoes have come from.

In that regard we are continuing to meet with Florida and Mexico exchanging information about growing areas, about whether they have any evidence of illness in their own states and particularly -- I mean in Mexico -- with this specific type of salmonella, the St. Paul, with the same genetic type. That information have been shared with the Mexican - we are sharing information with them on an ongoing basis they have been providing us information back that's been helping us and those meetings are continuing.

We've talked before on these calls about the complexities of trace backs and how some of our leads just go cold. We've also talked before about the optimism around the cluster - the single cluster that we discussed previously of 9 cases that trace back is so far holding up and we're hopeful that that will provide us information with regard to where the tomatoes in that particular cluster came from.

Some of the other information that we're getting I've told you before about the particular patient who originally said that she'd eaten one type of tomato and then on follow-up actually said it wasn't a Roma it was a red round. So that essentially meant that whole trace back fell apart. We had another one of those situations come up in the 36, 48 hours also in which a patient said

definitively they had bought the tomatoes from one place and then we discovered in the last day or so on further follow up questions that in fact yes they had bought tomatoes from that one place but they had also eaten tomatoes in two other places.

So again, when you think that you're getting close all of sudden it takes a different direction and all the information that you've gathered is really worthless, well not entirely worthless but it doesn't really help you get to the bottom, root cause of the problem.

It really is (unintelligible) of tracing fresh produce in particularly tomatoes. So in summary we are continuing with the trace and I want to echo Dr. Tauxe's words about thanks to state, local health authorities, CDC and FDA personnel who are literally working around the clock to try to beat this.

I know there is a great deal of frustration with many as to why hasn't FDA got this figured out yet. Frankly tomatoes are one of the hardest things we ever have to trace back and I think we have to acknowledge as I have on certain conversations with members of the media that we may not ultimately know the farm where these came from.

At this point we're not saying we're not going to know. We're continuing to work flat out assuming that we will get to that point, we're not pulling back.

You heard from Dr. Tauxe that we've had more cases added as the states have linked more cases to this without - within the profile of the dates of the outbreak. We're hopeful as we - that those numbers begin to come in and we learn more that maybe there's another cluster that's lurking in one of those states and we'll be working with CDC to get that information with the states,

because again if there is that may help us to triangulate back to where these tomatoes came from.

So we're still going flat out, we're still hoping we will get there but we're still not quite there yet. So with that Stephanie I'll hand back to you for some questions.

Stephanie Kwisnek: Great, thank you Dr. Acheson. At this time ladies and gentleman we'll take your questions and as always please limit yourself to one question and one follow up question. Please also state your name and affiliation. Operator we'll take the first question.

Coordinator: Thank you, we will now begin the question and answer session. If you would like to ask a question please press star, then 1. Please un-mute your phone and say your name clearly when prompted.

To withdraw your request press star, then 2, once again if you would like to ask a question please press star, then 1. One moment please. Press star, then 1 to ask your question. One moment.

Our first question comes from Annys Shin Washington Post, your line is open please ask your question.

Annys Shin: Hi I was just curious the case that you mentioned where the person realized they had eaten tomatoes somewhere else. Was that person part of the cluster by any chance?

Dr. David Acheson: No, they - when we - each one of these components has a trace back, we call it a leg, and each leg starts from an exposure and the cluster is nine people who got exposed in a single general vicinity. All the others have been single

patients so you're relying on memory of people remembering 2 or 3 weeks ago what tomatoes they ate and where they ate and so that was an individual case.

Annys Shin:

Okay, thanks.

Stephanie Kwisnek: Thank you Annys, operator next question.

Coordinator:

Our next question comes from Kathy Drexel New York Times.

Kathy Drexel:

It's actually New York One. Kathy Drexel New York One. Question if you were able to do the trace backs and figure out that the problems were with, Plum, Roma and Red Rounds to begin with then why are these trace backs becoming so difficult? Are you finding other similarities with tomatoes that people have been sickened with and other trends among this more than 300 that have been sickened?

And also from the list of states that are not included on those grown not associated, are you looking at those - is it easy to assume that those states are also being looked at?

Dr. Acheson:

Let me try to address the first question and it partly overlaps I think it with something that maybe Dr. Tauxe can add to. One of the first things that we gather during one of these outbreaks situations is first of all that the people that are getting sick from salmonella, you make that connection, salmonella St. Paul in this case.

Then the question is what caused it and here the question goes into what did people eat and when did they eat it and tomatoes come out as a significant

association and then you want to take it to the next layer of which types of tomatoes.

So it was clear from those initial studies that it was Roma, Plum or Red Round, couldn't differentiate between those three but that it was not Grape, Cherry or those ones that were still attached to the vine at the point of sale.

So that's based on questioning the patients in terms of the types of tomatoes that did eat or didn't eat. That then sort of gets you into the next part of this, which is ok so we think it's Roma, Red Round, or Plum, where did they come from. If you think back to spinach a couple years ago where we were doing the same sort of things, we knew it was spinach first, then 10 days later we knew where it had comes from.

So it's typical that you know what the food vehicle is first and then that doesn't change because that's based on the case control data and the information that has been generated by Center of Disease Control working with states and locals. Rob do you have anything you want to add to that?

Dr. Robert Tauxe: I think that covers it pretty well, Dave. The issue I think for many people is tomatoes are very common - commonly eaten and you know I probably have had tomatoes in several different forms myself in the last several days and it takes finding just someone who not only remembers what they had to eat and where they ate it but hopefully someone who didn't eat tomatoes everyday, so it can be decided fairly - so that it's fairly obvious which tomato it was that would have been associated with the illness. And that's finding those people and getting that information and then starting off on the trace back is - that's step 1 in the difficulty and then there is the difficulty in conducting the trace back.

Dr. David Acheson: Then the second part of your question which was around exclusion -- this

is David Acheson again. The way that we've approached that is essentially

anybody that is not on the exclusion list is theoretically part of -- could be part

of the outbreak in practice.

As I said earlier, it is very, very high likelihood that it's Florida or Mexico.

The way we have gone about these exclusions is the states and areas of the

world that are currently harvesting tomatoes have come to us and say, "Hey

we don't think our tomatoes are part of this outbreak and here's why," and

FDA has looked at that information and made the determination that, correct

they weren't harvesting at the time of the outbreak or they were harvesting a

different type of tomato, or the distribution of their product wasn't going to

the places where we're seeing illnesses and therefore they're not part of the

outbreak.

So that's been an active part in terms of growers have come to us with that

request and that information. So in theory if people haven't come forward it's

possible but I wouldn't like to leave you with the impression that because a

state isn't on that list that we think they're a high likelihood that's not true.

Does that make sense?

Kathy Drexel:

Yes that makes sense.

Stephanie Kwisnek: Thank you very much, operator we'll take the next question.

Coordinator:

Tiffany Hsu Los Angeles Times, your line is open.

Tiffany Hsu:

All right. Thanks so much for talking to me again. So my question is a

confirmation actually. I just want to know if its true that the FDA gets about

600 million to regulate, you know huge chunks of the nations food supply but

that the Depart of Agriculture gets one billion to just regulate, like meat and eggs, poultry, is that true?

Dr. Acheson: Yes that is, that's approximately right, those numbers are about right.

Tiffany Hsu: That's per year right?

Dr. Acheson: Yes.

Tiffany Hsu: Okay, and then do you know if the FDA plans to hold more inspections of

food processing plants in the future to maybe prevent more outbreaks?

Dr. Acheson: Yes, the short answer to that as you may well aware if you've been looking

into the appropriations the - a part of the new money for 2008 that's already

been received is being used to hire more inspectors as we move forward into

2009 with the new President's request. Again a portion of that money will be

used to hire more inspectors to do more inspections both domestically and

overseas.

But I want to just emphasize the FDA in terms of food safety is not arguing

that you can inspect your way out of these problems. The critical point is to

build a prevention and safety up-front and not simply to load up with

inspecting in the end. We're not going to either sample or inspect our way to

safety.

Tiffany Hsu: Okay, great thanks.

Stephanie Kwisnek: Thank you Tiffany, operator next question please.

Coordinator: Elena Vicca-Romen New York Times, you may ask your question.

Elena Vicca-Romen: Hi thanks for taking my call. In changing most recent date of infection from June 1st to June5th, I'm just wondering how many of these - the new - the 106 cases now being reported by CDC have - are people who have been infected you know recently within that time window?

Dr. Robert Tauxe: This is Rob Tauxe at CDC. We can't answer that question perfectly, because for some of them where the laboratory work has just been confirmed indicating that they are part of the outbreak the people haven't been interviewed yet to find out just when they might have been ill.

There are a number of cases that have had the onset of illness say 2 to 3 weeks ago and then a larger number that had an onset even farther back - longer ago than that. So I would say the majority of the new cases are back around say 3 weeks, 4 weeks ago when the outbreak appears to have at it's peak.

So there are some new cases that have had onset in the last 2 or 3 weeks that might suggest that there are still some cases continuing to occur. But most of this large increase in cases comes from cases that appear to have been further back in time.

Elena Vicca-Romen: Okay, thank you and just one quick follow-up. So just to clarify there, would you say that the outbreak already reached it's peak and now it's on the decline or is it ongoing, how would you - how would you characterize it?

Dr. Robert Tauxe: I think we have to say that's it's ongoing at this point its really too early to call the peak and we certainly cannot say that it's over. As we said that there are states that are now catching up on the laboratory work and so cases have been coming in rather quickly now and that there may be more such cases to

come in and we really can't predict what the final number's going to be or even what the shape of the curve is going to look like.

Elena Vicca-Romen: Thank you.

Stephanie Kwisnek: Thank you Elena, operator next call.

Coordinator: Mike Hughlett from The Chicago Tribune, you may ask your question.

Mike Hughlett: Hi, David I know you've been reluctant you know to say where the cluster of

nine cases was but - and as you know there's also - the Chicago Health

Department has mentioned that there's a cluster of nine cases here and I talked with them today and they're assuming that your cluster is the same as there's.

And they actually named the restaurant where their cluster came from today

the (Adobo Grill). So with that in mind can you say is this Chicago outbreak

at (Adobo Grill) is that the nine cases you're looking at too.

Dr. David Acheson: Nice try. No I -- as far as the FDA is concerned that remains commercial

confidential information and what the state chooses to share is up to them. But

while this outbreak is continuing we cannot discuss specifics about the cluster

beyond what we already have. Sorry

Mike Hughlett: Thank you.

Stephanie Kwisnek: Thank you Mike, operator we'll take the next question.

Coordinator: Thomas DaPakas your line is open.

Thomas DaPakas: Yes, hi, I was wondering if the tomato food safety guidelines being developed by the industry would address commingling of tomatoes from different origins and if you're concerned about that issue as you go forward?

Dr. David Acheson: This is David Acheson, I have not personally read the latest guidelines that the tomato industry is been putting out. I know that Center for Food Safety and Applied Nutrition is working on guidance for tomatoes and we can certainly follow up with you to get you more specifics on that.

Commingling per say is - I mean that - the act of that as long as it's done appropriately and you don't introduce infection while you're doing it isn't an issue. The issue is when you commingle you reduce the likelihood that you can trace anything back and if you're commingling tomatoes that are grown using good practices with tomatoes that are grown using not so good practices then you've essentially mixed some potentially bad tomatoes with some potentially good tomatoes.

So you know the key point here is not that commingling is a problem, the key point is if your going to commingle make sure you can trace them and make sure that the suppliers that you're commingling from are using good agricultural practices and preventative control.

(Thomas DaPakas): Thanks.

Stephanie Kwisnek: Do you have a follow-up question (Tom)? No, okay.

Coordinator: The questions been cleared. The next question is Louise Schiavone, CNN.

Louise Schiavone: Hello and thank you for taking my questions again today I have a couple of questions. First of all with respect to Mexico, when you ask Mexico regarding

whether or not they're having any illnesses there, what are their responses? Are you continuing to check the tomatoes coming across the border, have you found anything out of the ordinary about the produce your continuing to check?

Dr. David Acheson: This is David Acheson, Mexico is getting back to us with that specific information. I believe that they are - that they have - think that they have found some cases of salmonella St. Paul. I don't believe that they have been able to yet determine whether though if it is the same genetic fingerprint. I'm looking to my colleagues here to see if there's any more data on that but no that's essentially the status.

So we don't have that, that's part of the ongoing dialogue, yes we are continuing to test tomatoes as they are coming across the border and domestically, both. We've increased that and so far no, we have not found a positive.

Louise Schiavone: So just to follow up you're saying that Mexico does in fact, the authorities that you're in contact with, those authorities do in fact believe they may have in Mexico found cases of salmonella St. Paul but the laboratory work is still ongoing at this point, is that correct?

Dr. David Acheson: Yes, that's my understanding of what we know from Mexico but the fact that they found salmonella St. Paul is not that unusual, we have - I think rough - correct me if I'm wrong here - but I think last year there were 400 cases of salmonella St. Paul total in the United States of which three, with this particular genetic fingerprint.

So while salmonella St. Paul is a fairly rare isolate it doesn't mean that what the Mexicans found has anything to do with this contamination. It could be completely different.

Louise Schiavone: But it doesn't mean that it doesn't either. It's just unknown yet, right?

Dr. David Acheson: Right but please don't run inappropriately with the information. I'm putting out that yes they found salmonella St. Paul that's not such a surprise but I think it's important not to over interpret what that may mean in the context of public health. There's a real danger that through some of these press conferences that there is an over interpretation of what we're saying and I'm trying to make sure that doesn't happen.

Louise Schiavone: Okay sir, thank you.

Dr. David Acheson: Sure.

Stephanie Kwisnek: Thank you Louise, operator next question.

Coordinator: David Kerley ABC News, your line is open.

David Kerley: Dr. Acheson you sound much less optimistic about tracing this all the back.

This is the first time I've heard you say that you may never find it, why is

that? And secondarily we're getting different views from restaurants,

McDonalds puts it back on the menu, some have not, what should restaurants

be doing at this point?

Dr. David Acheson: Personally I'm still optimistic but I am trying to be realistic. As I pointed out just in some of my introductory comments, some trace backs that we thought were looking pretty good have been falling apart. As this continues on

the trace backs they get a little harder in terms of actually getting the information that we need, so as every day passes it gets a little more tricky, to be sure that people will have the records that we really need to track this down.

I'm still - I'm still optimistic but I'm trying to be realistic and just come to terms with the fact that we may not get there. That's not so unusual, particularly with tomatoes that we don't figure out a farm. We've been lucky with spinach and with peanut butter recently, which were high profile. We did get back to a facility and we found the bugs, in salmonella, we found them in the facility where the spinach was and found them on the farm.

So we'll see but I remain optimistic but I think trying to inject a note of realism, that it's possible we may not get there.

In terms of retailers we're trying to work very hard - we are working very hard with retailers to emphasis the importance to them informing their customers that the tomatoes that they are selling are okay to eat and they're not part of the outbreak. Retailers have recognized the importance of that. I can't speak to why one chain is going back with tomatoes and one chain is not. I guess that's a business decision but we're trying to ensure that retailers and restaurateurs have the right information so that if they choose - if they make the decision to go with tomatoes they know where their tomatoes are safe to get from.

David Kerley: Is there a right answer or a wrong answer for retailers at this point?

Dr. David Acheson: In terms of what, of safety?

David Kerley: In terms of having tomatoes on their menu.

Dr. David Acheson: No, I mean from a nutritional perspective you know tomatoes their healthy, that's - from that perspective great, if their on the menu. From a food safety perspective I'd like retailers to put tomatoes on their menus but make sure they come from a safe place. It gives consumers choice and it doesn't pose a public health threat. But they do need to ensure they know their suppliers, which is a key message that we've been trying to get over as well.

Stephanie Kwisnek: Thank you David, operator we have time for one more question.

Coordinator: Thank you, Clara Burke Associated Press, you may ask your question.

this is spurred any movement in that direction.

Clara Burke: Hi good afternoon and thanks for taking my call. I am wondering if given the ongoing outbreak there is a move toward drafting mandatory regulations for good agricultural practices and good manufacturing practices for tomatoes.

Obviously there are some industry standards that are voluntary but I'm wondering if you can speak to the call for a mandatory federal standard and if

Dr. David Acheson: Sure this is David Acheson again. If you look at the Food Protection Plan that we published in November we asked in that for a number of legislative authorities that we don't currently have and one of those under the prevention element was the authority to require preventive control for high-risk foods.

We'd find that in high-risk food and those that have been repeatedly associated with serious illness, salmonella is a serious illness tomatoes have been repeatedly associated with outbreaks. Therefore tomatoes would fall under this, as would a number of other types of fresh produce like certain types of leafy greens. So yes we have put word out that we would need - we need authority to require preventative control.

Exactly what that would look like would depend on exactly what the legislation looked like that Congress passed and what the rule making process did to it as we worked through. But at the high level we believe we need preventive controls for high-risk foods and tomatoes and other types of fresh produce would be part of that.

Clara Burke:

And at this point can you make any mention of the kind of preventative controls that you believe are necessary to prevent this sort of outbreak?

Dr. David Acheson: That - a lot has to do with as you point out making sure the practices throughout the production life cycle are acting in such a way to minimize the likelihood of contamination with pathogens, in this case with tomatoes, salmonella is obviously the main one. And that could occur anywhere from farm through to retail. There are certain areas with a higher vulnerability potentially on the farm during processing or packaging of tomatoes, or cooling of tomatoes, which would be clearly higher risk parts of that chain.

> Until we know the extent of the authority that we've been granted it's difficult to figure out exactly where you'd focus those preventative controls. I think at this point the key message is that we need them, we've asked for them and we don't yet have them.

Clara Burke:

I'm sorry I don't mean to be a pest but one follow-up question. Certainly requiring preventative controls is a pretty broad mandate so that could potentially mean either mandatory controls or voluntary controls correct?

Dr. David Acheson: No.

Clara Burke: I mean that the agency could presumably have the authority to check to see if

farms were following a set of voluntary guidelines, no?

Dr. David Acheson: No, what we're looking for here is mandatory. We're looking for the

authority to require preventative control. It would be mandatory. There'd be

no voluntary about it.

Clara Burke: All right, thank you very much.

Stephanie Kwisnek: And ladies and gentlemen that concludes today's media teleconference

thank you for your participation. The replay will be available in about an hour

and will be up for 3 days on our Web site. If you have any follow up questions

please don't hesitate to contact me, or any of my colleagues, we'll be happy to

help you. Have a good evening.

Dr. David Acheson: Thank you very much.

Coordinator: This concludes today's conference. Thank you for joining us and you may

wish to disconnect now, thank you.